Remarks

Claims 19-88 are currently pending. Claims 1, 8, 11, 12, 14-15, and 89-161 have been canceled without prejudice or disclaimer. Claims 19 and 53 have been amended to more clearly claim embodiments Applicants regard as the invention. The amended claims are supported throughout the specification. Therefore, no new matter has been introduced.

I. Restriction Requirement

Applicants thank the Examiner for acknowledging Applicant's timely election with traverse in Paper No.5. Despite the arguments presented by Applicants, the Examiner has rendered the restriction requirement final and withdrawn from further consideration claims 1, 8, 11, 12, 14-15, 44-52, 80-88, and 90-161, as allegedly being drawn to non-elected subject matter. As mentioned above, Applicants have canceled claims 1, 8, 11, 12, 14-15, and 90-161 without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of the canceled claims in one or more continuing applications.

Further, Applicants request rejoinder of the claims of Group VIII (claims 44-52 and 80-88) if the pending claims of Group III (claims 19-43 and 53-79) are found allowable. In light of the decisions in *In re Ochiai,* 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer,* 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. *See* 1184 OG 86 (March 26, 1996). Specifically, the notice states that:

> [I]n the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

Id. Accordingly, if the claims of Group III are found allowable, Applicants respectfully request that the claims of Group VIII be rejoined and examined for patentability. *See* also M.P.E.P. § 821.04.

II. IDS references

The Examiner did not consider references AA-AG and AJ-AS submitted by Applicants on November 19, 2001 and April 26, 2002. The Examiner alleges that some of the references were not provided. *See,* Paper No.6, page 3, paragraph 3. Applicants respectfully point out that reference AS was sent with the Information Disclosure Statement on April 26, 2002. In addition, the Information Disclosure Statement submitted on November 19, 2001 stated that copies of references AA-AR were submitted by Applicants or cited by the Examiner in connection with United States Patent Application Serial Nos. 09/224,110, filed March 31, 1998, and 08/469,667, filed June 6, 1995, to which the instant application claims priority under 35 U.S.C. § 120. Pursuant to 37 C.F.R. § 1.98(d), the Examiner was directed to the files of United States Patent Application Serial Nos. 09/224,110 and 08/469,667 for copies of references AA-AR. Nonetheless, Applicants have submitted herewith copies of all references listed on the new PTO/SB/08. Applicants respectfully request that the submitted references be considered and that Applicants be notified of such consideration.

The Examiner has indicated that references AN, AO, AQ, and AR were not considered as the publication date is required to be listed. *See*, Paper No.6, page 3, paragraph no.3. Therefore, Applicants have submitted a new PTO/SB/08 form which now recites the publication date for references AN, AO, AQ, and AR. Applicants respectfully request that the submitted references be considered and that Applicants be notified of such consideration.

The Examiner further indicated that references AE, AJ, and AS were not considered because they are "not required to be listed in the PTO-1449." *See*, Paper No.6, page 3, paragraph no.3. Applicants respectfully point out that under 37 C.F.R. § 1.97 an information disclosure statement "shall be considered by the Office" if filed within an acceptable time period and in accordance with the requirements of 37 C.F.R. § 1.98. In addition, Applicants respectfully point out that the citation of a pending U.S. application in an information disclosure statement is indeed appropriate pursuant to C.F.R. §§ 1.98(a)(2)(iii) and 1.98 (b)(3). Further, Applicants point out that the Information Disclosure Statement submitted on April 26, 2002 was filed pursuant to 37 C.F.R. 1.97(b)(3) and fulfills the requirements of 37 C.F.R. § 1.98. Accordingly, Applicants contend that refusing to consider references AE, AJ, and AS is improper.

Therefore, Applicants respectfully request that the Examiner consider references AE, AJ, and AS (listed on the PTO/SB/08 form submitted herewith) and notify Applicants of such consideration.

III. Rejection of Claim 89 Under 35 U.S.C. § 102

The Examiner has rejected claim 89 under 35 U.S.C. § 102(b) as being anticipated by Oda et al., *J. Biol. Chem.* (1993), 268 (8):5929-5939. *See,* Paper No. 6, pages 3-4, paragraph no.5. More particularly, the Examiner asserts at page 3, paragraph no.5 of the Office Action:

> Oda et al. discloses that antibodies against RI-H were raised in rabbits (see pg. 5930, column 2, third paragraph). The amino acid sequence of RI-H comprises SEQ ID NO:16 as indicated in the search report (See pg. 5934, fig. 2 and the Attached search report). It appears that they are the same antibody since the antibody only binds to a portion of the protein and not the entire protein. This was well known in the art at the time of the instant invention. Thus, the teachings of Oda et al. anticipate the limitations of claim 89.

Preliminarily, Applicants respectfully point out that the amino acid sequence of rat RI-H disclosed in the Oda et al. reference does not comprise the entire amino acid sequence set forth in SEQ ID NO:16, as alleged by the Examiner. In fact, the sequences are only 77% identical. *See,* Search Report sent by Examiner with Paper No.6. Clarification is respectfully requested.

Nonetheless, in response to the Examiner's rejection, Applicants respectfully disagree, but in the interest of facilitating prosecution, Applicants have canceled claim 89 without prejudice or disclaimer rendering the rejection moot. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of claim 89 under 35 U.S.C. § 102(b).

IV. Rejections Under 35 U.S.C. § 103

Claims 19-21, 23, 41-43, 53-57, 59, and 77-79

The Examiner has rejected claims 19-21, 23, 41-43, 53-57, 59, and 77-79 under 35 U.S.C. § 103(a) as unpatentable over Oda et al., *J. Biol. Chem.* (1993), 268 (8):5929-5939.

See, Paper No.6, pages 4-5, paragraph no.7. In particular, the Examiner asserts at page 5, first paragraph, of the Office Action:

> The amino acid sequence of RI-H comprises SEQ ID NO:16 as indicated in the search report (See Attached search report). The antibody against RI-H was raised in rabbits and a hybridoma was used to produce a monoclonal antibody to L-29 (see pg. 5930, column 2, third paragraph).
>
> Thus, the antibody used by Oda et al. is suggested to be the same antibody as claimed in the instant invention.
>
> One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the antibody of Oda et al. to against the protein whose sequence consists of amino acid residues 1-323 of SEQ ID NO:16 because it appears that they are the same antibody since antibody only binds to a portion of the protein, not the entire protein. This was well known in the art at the time of the instant invention. Thus, it would have been *prima facie* obvious to obtain the isolated antibody as claimed.

Preliminarily, Applicants respectfully point out that claims 19 and 53 have been amended to recite "isolated human antibody" (emphasis added). In addition, Applicants respectfully point out that the amino acid sequence of rat RI-H disclosed in the Oda et al. reference does not comprise the entire amino acid sequence set forth in SEQ ID NO:16, as alleged by the Examiner, but is merely 77% identical to SEQ ID NO:16.

To establish obviousness, three basic criteria must be met. As set forth in M.P.E.P. § 2143:

> First, their must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be reasonable expectation for success. Finally, the prior art reference (or references combined) must teach or suggest all the claim limitations. M.P.E.P. § 2143 at 2100-122.

Therefore, to establish obviousness in the instant case, the Examiner must demonstrate that there is some suggestion or motivation to modify the teachings of Oda et al. in order to satisfy all of the limitations of the rejected claims. More particularly, the Examiner must at least demonstrate that there is a suggestion or motivation to modify the teachings of Oda et al. to generate human antibodies which would specifically bind the polypeptide of SEQ ID NO:16.

Applicants respectfully point out that one skilled in the art, given the disclosure of Oda et al., would not be motivated to generate a human antibody against the polypeptide of SEQ ID NO:16. Oda et al. merely describe generating rabbit antibodies to rat polypeptides. More particularly, Oda et al. teach antibodies that were generated against two rat lectin proteins, RI-H (*i.e.*, L-36) and L-29. Based on the teachings of Oda et al., it appears that the antibodies were only generated against these rat proteins to detect the polypeptides in a western blot. *See,* pages 5939, second column to page 5940. The Oda et al. reference clearly does not explicitly or implicitly suggest or motivate the skilled artisan to generate a human antibody to either of these rat proteins or the polypeptide of SEQ ID NO:16. Therefore, since there is no suggestion to modify the teachings of Oda et al. in order to satisfy all of the limitations of the rejected claims, the teachings of the Oda et al. reference do not render the claimed invention obvious.

Further, the teachings of Oda et al. do not teach or suggest a human antibody that specifically binds a protein comprising the amino acid sequence of SEQ ID NO:16. Applicants respectfully point out the the use of the term "specifically" with reference to antibody binding is routinely used by persons of ordinary skill in antibody arts. To one skilled in the art, "specific" language means that the claimed antibodies preferentially bind to their target antigen. Therefore, Applicants submit that the skilled artisan would read "specifically" in the rejected claims to mean that the claimed antibodies preferentially bind to their target antigen, the protein of SEQ ID NO:16. Accordingly, as long as a human antibody generated against the polypeptide of SEQ ID NO:16 preferentially bound the polypeptide of SEQ ID NO:16, one skilled in the art would conclude that the antibody is specific. As mentioned above, the Oda et al. reference cited by the Examiner merely describes rabbit antibodies to rat polypeptides. The Oda et al. reference clearly does not explicitly or implicitly suggest or motivate the skilled artisan to generate a human antibody that would specifically bind the polypeptide of SEQ ID NO:16 as is required by the rejected claims. Thus, the teachings of the Oda et al. reference do not render the claimed invention obvious

In view of the above, Applicants respectfully request that the rejection of claims 19-21, 23, 41-43, 53-57, 59, and 77-79 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Claims 24, 30-31, 60, and 66-67

The Examiner has rejected claims 24, 30-31, 60, and 66-67 under 35 U.S.C. § 103(a) as being unpatentable over Oda et al., *J. Biol. Chem.* (1993), 268 (8):5929-5939 in view of Imani et al. (U.S. Patent No. 5,766,856). *See,* Paper No.6, page 5, paragraph no.8.

Applicants respectfully traverse this rejection.

As pointed out above, the Oda et al. reference does not explicitly or implicitly suggest or motivate the skilled artisan to generate human antibodies that would specifically bind the polypeptide of SEQ ID NO:16. While the Imani et al. reference teaches a method of labeling an antibody to a target protein, the disclosure in this reference does not cure the defects of the Oda et al. reference discussed above. Therefore, Applicants respectfully request that the rejection of claims 24, 30-31, 60, and 66-67 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Claims 22, 25-29, 32-40, 58, 61-65, and 68-76

The Examiner has rejected claims 22, 25-29, 32-40, 58, 61-65, and 68-76 under 35 U.S.C. § 103(a) as being unpatentable over Oda et al., *J. Biol. Chem.* (1993), 268 (8):5929-5939 in view of Imani et al. (U.S. Patent No. 5,766,856) and Co et al. (U.S. Patent 5,714,350). *See,* Paper No.6, page 6, paragraph no.9.

Applicants respectfully traverse this rejection.

As pointed out above, the Oda et al. reference does not explicitly or implicitly suggest or motivate the skilled artisan to generate human antibodies that would specifically bind the polypeptide of SEQ ID NO:16. While the Imani et al. reference teaches a method of labeling an antibody to a target protein and the Co et al. reference teaches methods of producing altered immunoglobulins, the disclosure in these reference do not cure the defects of the Oda et al. reference discussed above. Therefore, Applicants respectfully request that the rejection of claims 22, 25-29, 32-40, 58, 61-65, and 68-76 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Conclusion

In view of the amendments and remarks above, Applicants believe that this application is in condition for allowance. If in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below.

If there are any fees due in connection with the filing of this paper, please charge the fees to Deposit Account No. 08-3425.

Respectfully submitted,

Dated: 21 October 2002

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MMW/LJH/SA/vr

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Yu et al.
Application Serial No.: 09/988,292
Filed: November 19, 2001
Title: Colon Specific Genes and Proteins

Attorney Docket No.: PF160D2
Art Unit: 1637
Examiner: Tung, J.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

19. (Once Amended) An isolated human antibody or portion thereof that specifically binds to a protein selected from the group consisting of:

(a) a protein whose sequence consists of amino acid residues 1 to 323 of SEQ ID NO:16;

(b) a protein consisting of a fragment of SEQ ID NO:16, wherein said fragment comprises at least 30 contiguous amino acid residues of SEQ ID NO:16; and

(c) a protein consisting of a fragment of SEQ ID NO:16, wherein said fragment comprises at least 50 contiguous amino acid residues of SEQ ID NO:16.

53. (Once Amended) An isolated human antibody or portion thereof produced by immunizing an animal with a protein selected from the group consisting of:

(a) a protein whose sequence comprises amino acid residues 1 to 323 of SEQ ID NO:16;

(b) a protein whose sequence comprises at least 30 contiguous amino acid residues of SEQ ID NO:16; and

(c) a protein whose sequence comprises at least 50 contiguous amino acid residues of SEQ ID NO:16,

wherein said antibody or portion thereof specifically binds to the amino acid sequence of SEQ ID NO:16.